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Survey Finds 1/3 Of Device Firms Don't Measure The Cost Of Quality. Here's How A Case For Quality Initiative Might Help

by [Shawn M. Schmitt](#)

A recent device industry survey shows that 33% of manufacturers are likely wasting money on quality efforts that are ineffective because they're not calculating the cost of quality. The survey comes under the auspices of a Case for Quality workgroup that is looking for best ways to engage leadership at device firms in quality activities. The group says it will use the survey results to inform its work as it pens a playbook of best practices for engaging leaders that will, among other things, stress the importance of knowing the cost of quality.

A third of medical device manufacturers are likely wasting money on quality efforts that are ineffective because they're not calculating the cost of quality, a recent industry survey shows.

Of the 88 survey-takers who responded to the declaration, "At my company, we formally measure the cost of quality," a combined 33% said they "disagree" (20%; 18 responses) or "strongly disagree" (13%; 11). (See Question No. 9 in the exhibit below.)

Device-makers should "measure cost of quality to make sure that they're doing it effectively and efficiently," said Pat Shafer, managing director for health care and life sciences at business and financial consultancy Grant Thornton LLP.

"If a company isn't measuring how it's spending its money, it might be spending very inefficiently – spending a lot of money on quality and not getting results," Shafer told *Medtech Insight* in a 25 July interview.

The American Society for Quality (ASQ) [defines](#) "cost of quality" as "a methodology that allows an

organization to determine the extent to which its resources are used for activities that prevent poor quality, that appraise the quality of the organization's products or services, and that result from internal and external failures."

Having cost-of-quality information helps a company see where it can save money by improving particular processes.

"Companies invest in a quality organization to make sure they're compliant, to make sure that the product quality is good, and that there's continuous improvement," Shafer said. "Firms want to measure that cost, and measure it at a granular level so they can spend their money effectively. In other words, does it make sense to invest in a huge CAPA [corrective and preventive action] program? Does it make sense to invest in change control or some other quality area?"

"The survey does show that there are a couple of areas where firms are less effective. There's definitely room for improvement." – Pat Shafer

Meanwhile, a combined 39% of survey respondents "agree" (16%; 14 responses) or "strongly agree" (23%; 20) that their company measures the cost of quality. The largest slice of survey-takers – 28% (25) – gave an answer of "neutral."

The survey, conducted in March and April, was coordinated by the Medical Device Innovation Consortium (MDIC) as part of its ongoing [Case for Quality](#) work with the US Food and Drug Administration.

Outcomes from the anonymous, unscientific questionnaire serve as a general bellwether of quality trends at firms. A majority of respondents (80%) serve in leadership roles in the device industry.

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The survey results suggest a clear movement toward quality in some areas by device manufacturers. For example, a strong majority of leaders are promoting quality at their firms (Question No. 1) and reviewing objective measures to assess quality performance (Question No. 5), and most companies are making sure that workers understand how quality impacts their jobs

(Question No. 3).

Yet the survey shows that there is still more work to do – and not only when it comes to measuring the cost of quality.

For example, Question No. 8 results find that less than half of device firms – 47% – focus on preventing problems. And outcomes from Question No. 6 show that more than a quarter of survey-takers – 27% – gave an answer of "neutral" when answering whether company leaders "regularly engage with staff to understand the behaviors that drive good quality and quality failures."

"The survey does show that there are a couple of areas where firms are less effective, such as measuring the cost of quality and leaders making sure they're out on the shop floor engaging," Shafer said. "So there's definitely room for improvement."

Leadership Engagement Playbook

The recent survey comes under the auspices of a Case for Quality workgroup that is looking for best ways to engage leadership at device firms in quality activities.

Last year, the group set a goal to have 85% of CEOs engaged in quality work by 2020. (Also see ["With New Initiatives, Case For Quality Embarks On Mission To Create 'Safe Space,' Engage CEOs, #makeCAPAcool"](#) - Medtech Insight, 29 Jun, 2018.)

The workgroup – of which Grant Thornton's Shafer is co-leader – plans to use the results of the survey to inform its work as it pens a playbook for industry on best practices for engaging leaders.

The playbook will strongly focus on what the group calls the "areas of greatest need" for device-makers, including measuring the cost of quality, pushing leaders to understand the link between behaviors and quality outcomes, and moving from a reactive stance to a proactive one.

"This playbook will give firms the tools they need to do quality right, and do it well," Shafer said. For example, "one of the important activities within the playbook will be to make sure that leaders, as they work on pushing their quality agenda, conduct surveys within their companies to verify whether employees are aligned with their leadership's thinking."

Quality "starts from the top." – Joe Sapiante

Joe Sapiente, VP of quality assurance and regulatory affairs at device manufacturer [Hologic Inc.](#), further explained: "Very similar to the Library of Successful Quality Practices, [the playbook] will give folks an opportunity to look at how other companies are approaching quality and leadership – and if they're on a path and they're looking to improve, [the playbook will offer] some ways to do that."

The [Library of Successful Quality Practices](#) was developed by device industry advocacy group AdvaMed in 2015 as a resource for manufacturers to enhance their quality processes. (Also see "[Guest Column: Understanding AdvaMed's 'Library Of Successful Quality Practices'](#)" - Medtech Insight, 1 Apr, 2015.)

Sapiente, who co-leads the Leadership Engagement workgroup with Shafer, says users of the playbook will be able to "pick and choose" what works best for them.

"You can take parts of everybody's best practices [for leadership engagement with quality] and create a program for yourself, or you can shamelessly steal somebody else's program and copy it," Sapiente said at a Case for Quality forum in Arlington, VA, in June.

If a particular approach is in the playbook, that means "there's a lot of evidence out there that it works," he added. "So there's nothing wrong with saying, 'I want to use the playbook that was developed by this other company.'"

Once finished, the workgroup will conduct a six-month pilot of the playbook to "identify leading practices," Sapiente said.

The group is reaching out to device-makers to adapt material for the playbook and volunteer for the pilot.

Sapiente urges firms to take part, noting that companies whose leadership creates a "quality culture throughout the organization, at all levels of the organization," is on the right track.

"It all starts from the top," he said.